

Application No.: 10/528,443

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Docket No.: 595222000100

REMARKS

Claims 1-18 are pending in this application. By this amendment, claims 2 and 12 are cancelled, new claims 19 and 20 are added, and claims 1, 4-11, and 13-18 are amended. No new matter is added by the amendments. Entry of the amendments and reconsideration of the application is respectfully requested in view of the above amendments and the following remarks.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

A. Objection to the Specification

As required by the Office Action, the specification is amended to add a recitation of a cross-reference paragraph relating the priority of the present application to application No. PCT/IN03/00414 filed Dec. 30, 2003.

B. Objection to the claims

As required by the Office Action, claims 1, 5-11 and 13-18 are amended to correct informalities. The misspelled term "crystalline" is replaced with the correctly spelled "crystallin" throughout the claims.

In claims 1(c), 15 and 16 "the" is inserted between "in" and "presence".

In claims 7-8, "enhance" is grammatically corrected to "enhances."

In claim 9, the term "maybe" is replaced with "is."

In claim 1, "biological" is replaced with the grammatically correct "biologically".

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C. Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 14-16 stand rejected due to alleged lack of enablement as the Examiner states that the specification does not provide enhancement of alphaA-crystallin chaperone activity with Arg.HCl.

In response, Applicants amend claim 14 to recite: "[a] method as claimed in claim 1, wherein the mutant α A-crystallin is less sensitive to Arg.HCl than α B-crystallin, thereby enhancing the chaperone activity." Support for the amended claim is found *inter alia* at page 9, line 30 to page 10, line 20 of the Specification.

Claims 15 and 16 are amended to depend from claim 1 (and not claim 14). Therefore, this ground for their rejection is moot.

Withdrawal of the rejection of claims 14-16 under 35 U.S.C. 112, ¶ 1, is respectfully requested.

D. Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-18 stand rejected due to alleged indefiniteness. In response, Applicants make the following amendments:

As required by the Office Action, claim 1(a) is amended to delete references to methods carried out "by conventional methods." In claim 1(b), "reacting" is replaced with "mixing." Claims 1(b) is further amended to recite: "mixing α -crystallin with Arg.HCl and either insulin or ζ -crystallin" – thus providing clarification that the claimed method requires α -crystallin + Arg.HCl + (insulin or ζ -crystallin). The limitations of pH=7.4 and "presence or absence of DTT" are deleted. The limitation wherein the enhancement is observed by fluorescence spectrophotometer is also deleted from claim 1(c).

New claim 19, which depends from claim 1, is directed to observation of the enhancement by fluorescence spectrophotometer. Support for claim 19 is found in the originally filed claim 1 and page 12, etc. of the Specification.

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New claim 20, which depends from claim 1, is directed to the mixing carried out in the presence of dithiothreitol ("DTT"). Support for claim 20 is found in the originally filed claim 1 and page 12, etc. of the Specification.

Claim 2, considered redundant, is cancelled.

Claim 4, objected to for reciting a range within a range specified in claim 3 is amended to depend from claim 1. The ground for rejection of claim 4 is moot.

Claim 6 is amended to depend from claim 1, instead of claim 5. The ground for rejection of claim 6 is moot.

Claims 8, 16 and 18 are objected to for not limiting claims 7, 15 and 17 respectively. Claims 8, 16 and 18 are amended to depend from claim 1, instead of claim 5. The ground for rejection of claims 8, 16 and 18 are moot.

Claim 9 is amended to depend only from claim 7 and recite: " wherein the aggregation system comprises of insulin, or ζ -crystallin. The objected to term "related compounds" is deleted.

Claims 12-13 are rejected for use of terms "subtle" and "significant" and being redundant to claim 1. In response, Applicants cancel claim 12. Claim 13 is amended to depend only from claim 1 and recite: "wherein in the presence of Arg.HCl the molecular mass of α -crystallin is reduced to ~360 kDa." Limitations using the terms "subtle" and "significant" are deleted. No new matter is added. Support for the amendment is found in the originally filed claims and page 9, lines 20-22 of the Specification.

Claims 14-16 are objected to for reciting "mutant" subunits of alpha-crystallin without proper antecedent basis. In response, Applicants amend claim 1 to recite: " α -crystallin (comprising α A-crystallin or an active mutant thereof and α B-crystallin or an active mutant thereof)." Support for active mutant forms of α A-crystallin and α B-crystallin is found at page 9, line 30 to page 10, line 20 and elsewhere in the Specification. No new matter is added by these amendments. In light of the recitation of active mutant forms of α A-crystallin and α B-crystallin in claim 1, claims 14-16 now have proper antecedent basis.

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Further, claim 15 is amended to depend only from claim 1 and not claim 14.

Claims 15 and 16 were rejected for lack of clarity of the term "protection of." In response, Applicants amend claims 15 and 16 to recite: "wherein a protective effect of mutant α B-crystallin is about 75% that of wild type α B-crystallin in the presence of Arg.HCl." Support for active mutant forms of α A-crystallin and α B-crystallin is found at page 9, line 30 to page 10, line 20 of the Specification. Applicants submit that claims 15 and 16, as amended particularly points out and distinctly claims the subject matter recited therein.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, paragraph 2.

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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to *Deposit Account No. 03-1952* referencing docket no.

595222000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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